REMARKS

In reply to the Office Action dated April 4, 2005, claims 3, 4, 11, 15, and 18 are currently under examination in the Application. By the above amendment, claims 15 and 18 have been amended. Support for the amendments can be found throughout the application as filed, for example, at page 30, lines 8-12, and page 92, line 25- page 93, line 2. No new matter has been added. The above amendment is not to be construed as acquiescence to the stated grounds for objection/rejection and is made without prejudice to prosecution of any subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application.

Rejections Under 35 U.S.C. § 112, second paragraph (indefiniteness)

Claims 3, 4, 11, 15, and 18 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The Examiner is of the opinion that the phrase "degenerate variants thereof" is intended to encompass different polynucleotides which encode the same polypeptide sequence as encoded by SEQ ID NO: 302 or 303. However, the Examiner alleges that this term is not defined in the specification and "one of skill in the art would not be apprised of how different a sequence may be from the base sequence and still be included within the scope of the claims."

Applicants traverse the rejection on the following grounds.

The Examiner cites page 26 of the specification to support the argument that the meaning of the term "degenerate variant" is not as Applicants intend. It is submitted that the Examiner is misreading the disclosure on page 26. The paragraph bridging pages 25 and 26 specifies that according to an aspect of the invention, polynucleotide compositions are provided that comprise some or all of the specified nucleotide sequences, or complements or degenerate variants of those sequences. The subsequent disclosure in the second and third paragraphs of page 26 relates to polynucleotide variants of other related embodiments (line 8). Preferred percentage identities of those variants to the specified sequences are given. Reference to codon degeneracy at lines 16-17 in relation to these variants reflects the fact that some sequences may be more highly related than suggested by their sequence identity because they may encode the

same amino acid residue at a particular codon in spite of having a different sequence. The third paragraph on page 26 (lines 18-23) specifies typical changes that can be made to the specified polynucleotide sequences to provide the polynucleotide variants described in the previous paragraph (lines 8-17). Thus, the passages at lines 8-23 on page 26 relate to polynucleotide variants of the other related embodiments, rather than the degenerate variants referred to at line 4.

With regard to the passage quoted by the Examiner on page 30, the Examiner appears to be combining (and confusing) disclosure relating to degenerate variants with separate disclosure relating to alleles. The passage at lines 8-12 of page 30 clearly relates to polynucleotides that encode the same polypeptide, but which differ in their codon usage. The passage at lines 13-18 of page 30 relates to alleles, which are a different type of variant to degenerate variants. An allele is one of two or more alternate forms of a gene that can have the same locus on homologous chromosomes and are responsible for alternative traits. The distinction between the two passages is made clear by the word "Further" at the end of line 12.

Applicants aver that the term "degenerate variant" is used in the specification in accordance with the normal meaning of this term as understood by a person of ordinary skill in the art, and as specified in the quoted passage from the standard textbook Molecular Biology of the Cell, cited in Applicants' previous response.

Notwithstanding the above remarks, the term "degenerate variant" has been deleted from claim 18 and replaced with wording which specifies a sequence that varies from SEQ ID NO: 302 or 303 due to differences in codon usage as a result of the degeneracy of the genetic code. This wording is based on the passage at page 30, lines 8-12, which makes it clear that a particular polypeptide may be encoded by many different nucleotide sequences as a result of the degeneracy of the genetic code, and that such nucleotides are within the scope of the invention. This amendment is made solely to expedite prosecution and without prejudice.

The Examiner also maintains her rejection of claim 15, alleging that the term "at least" identifies a minimum value implying no upper limit while the term "about" constrains the length to close to the stated number.

Applicants traverse the rejection for reasons already of record. Without acquiescing to the rejection and solely to expedite prosecution, Applicants have removed the term "about" from claim 15. Applicants submit that it is clear from the description at page 33, lines 3-11, and lines 17-21, and from page 34, lines 8-11, that probes or primers for nucleic acid hybridization may be of any length from 10 nucleotides up to full length sequence. Consequently, it is submitted that the scope of the claim is clear from the description.

Further concerning claim 15, the Examiner appears to be rejecting the claim because oligonucleotide primers are specified. As such, the Examiner appears to believe that it is necessary to limit these to primers that could be used to amplify the specified sequence.

Without acquiescing to the rejection, claim 15 has been amended solely to expedite prosecution, to specify a kit comprising at least one oligonucleotide, wherein the oligonucleotide is a primer or a probe. Basis for this amendment is found at page 92, line 25 – page 93, line 2. It is clear from the specification that diagnostic methods may involve use of oligonucleotide primers for PCR, or oligonucleotide probes for hybridisation assays, and that diagnostic kits may include such reagents (see page 85, lines 9-10, page 90, line 17 – page 91, line 21, page 92, lines 15-17, and page 92, line 25 – page 93, line 2). Where oligonucleotide probes are used for hybridisation assays they may hybridise to the same strand, or immediately adjacent one another.

The Examiner is of the opinion that it is unclear what a "complement" of the sequence is limited to in claim 18. Applicants traverse the rejection and submit that part (c) of claim 18 specifies the complement of the sequence provided in SEQ ID NO: 302 or 303. It is submitted that this wording is clearly referring to a fully complementary sequence across the whole length of SEQ ID NO: 302 or 303, and that this would be apparent to the skilled person.

Applicants submit that the claims particularly point out and distinctly claim the subject matter which Applicants regard as the invention and respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 112, first paragraph (enablement)

Claims 3, 4, 11, 15, and 18 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one of skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In particular, the Examiner contends that there are an enormous number of polynucleotides, vectors, and host cells to be experimentally tested in order to make a useful polypeptide encoded by SEQ ID NO: 302 or 303 or degenerate variants thereof (page 5, lines 17-19). The Examiner also comments that another experimentation requirement is the determination of a useful activity for SEQ ID NO: 302/303. Throughout the rejection, the Examiner refers to "the instantly claimed methods" (page 6, line 11), "a polypeptide to be used as claimed" (page 6, lines 24-25), "the methods of claim 18 or 37" (page 7, last line), "the claimed polypeptides or methods of their use" (page 9, lines 7-8), "the claims are directed to encompass polypeptides of a particular sequence" (page 9, 4th line from bottom), "active polypeptide for use in the claimed methods" (page 10, lines 2-3), and "the claimed methods" (page 10, line 5).

Applicants traverse the rejection on the following grounds. Applicants do not agree with the Examiner's assertion that production of the polypeptides encoded by SEQ ID NO: 302 or 303 is not enabled, or that a useful activity for these polypeptides is not enabled. However, it is pointed out to the Examiner that no methods or polypeptides are presently claimed. Consequently, there is no requirement to enable production of the polypeptides, or an activity for such polypeptides.

The present claims relate to an isolated polynucleotide, an expression vector, a host cell, a composition comprising a polynucleotide and a physiologically acceptable carrier or immunostimulant, and a diagnostic kit comprising oligonucleotide primers or probes. Production of the specified polynucleotides, host cells, compositions and diagnostic kits is enabled by the application since these can be produced using standard techniques well known to the skilled person, and described in the specification at page 30, line 19 – page 32, line 26, page 34, lines 14-20, page 42, line 24 – page 52, line 15, page 70, line 6 – page page 73, line 11,

page 75, line 18 – page 82, line 3, page 92, line 15 – page 93, line 2, and described in publications referred to in the specification at page 10, lines 18-27.

Furthermore, an illustrative utility for polynucleotides of SEQ ID NO: 302 or 303 (and for oligonucleotide primers or probes comprising any continuous portion of these sequences from 10 nucleotides up to the full length sequence) is also enabled in the application. For example, such sequences may be used to detect the level of mRNA expression, which is also indicative of the presence or absence of a cancer, or of the progression of cancer. The use of the sequences for such methods is described at page 7, lines 6-27, and in detail at page 33, line 3 – page 34, line 13, and at page 85, lines 9-10, and page 90, line 17- page 93, line 2. Applicants submit, therefore, that the skilled artisan would readily understand how to make and use the subject matter of the claims. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejections Under 35 U.S.C. § 102(a)

Claims 3, 4, 11, 15, and 18 stand rejected as allegedly being anticipated under 35 U.S.C. § 102(a) over Frudakis (WO 98/45328). In particular, as further outlined in her rejections under 35 U.S.C. § 112, second paragraph, the Examiner alleges that because the terms "degenerate variants" appear to include deletions, insertions, mutations, substitutions, *etc.* and "complement" allegedly does not necessarily mean full-length complements of the recited sequences, the claims are then anticipated by the polynucleotide of Frudakis that encodes the polypeptide of SEQ ID NO:188, which polynucleotide allegedly has significant identity to the claimed polynucleotides of SEQ ID NO:302 and 303. Applicants note that it is unclear which sequence the Examiner is refering to since SEQ ID NO:188 is a polynucleotide not a polypeptide.

Without acquiescing to the rejection, claim 18 has been amended, without prejudice, such that the specified variants of SEQ ID NOs: 302 and 303 differ from those sequences due to differences in codon usage as a result of the degeneracy of the genetic code. As noted above, Applicants submit that part (c) of claim 18 specifies the complement of the sequence provided in SEQ ID NO: 302 or 303 and it is clear that this wording is referring to full

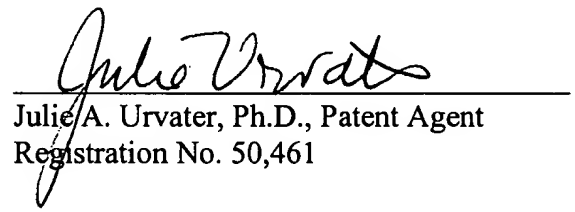
length sequence complementary to SEQ ID NO: 302 or 303. Accordingly, Applicants maintain that the amended claims are not anticipated by the disclosure of Frudakis. Applicants reserve the right to prosecute any subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application. Reconsideration and withdrawal of the rejection are respectfully requested.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that all the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC



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